



## *Istituto Superiore di Sanità*

### ***SUBCONTRACT of Specific GRANT CHAFEA No 676969 - 'Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation (VISTART)'***

This sub-contract is made and entered into force by and between:

The Istituto Superiore di Sanità ("ISS") established in Italy - Rome Viale Regina Elena, 299 00161 VAT No 03657731000 represented by its Financial Manager Dr. R.M. Martoccia

And

Università Cattolica del Sacro Cuore ("the sub-contractor") established in Italy - Milan Largo Agostino Gemelli, 1 20123, VAT Number 02133120150 represented by its Managing Director Prof. M. Elefanti.

Hereinafter designated collectively as Parties

Whereas

- ⇒ the contractor has signed with the CHAFEA specific GRANT No 676969 to carry out the joint action called "VISTART" hereinafter referred to as the "Specific CHAFEA-Contract";
- ⇒ the contractor in the Specific CHAFEA - Contract has foreseen a Subcontract to achieve quality and safety standardization of the inspection, authorization and vigilance systems adopted by EU Member States, methodological support for the implementation of both face-to-face and e-learning training courses addressed to European inspectors is necessary.
- ⇒ the contractor wants to entrust the subcontract to the "Università Cattolica del Sacro Cuore", because it has unique skills and experience, in order to perform the requested service.
- ⇒ the Parties consider the Specific CHAFEA-Contract mentioned above as forming an integral part of this Subcontract;

*the Parties do hereby agree as follows:*

#### **Article 1**

Under the terms of this subcontract, ISS entrusts the sub contractor, who accepts, to contribute to the achievement of the requirements of Specific CHAFEA-CONTRACT together with the contractor.

In particular, the sub contractor undertakes to perform, with due diligence, the service as follows:

- the design of both the e-learning and face-to-face course for the inspectors with an emphasis on content;
- the creation of the course materials;
- the supply of teachers for the face-to-face course;
- the development of tools for the efficacy and quality assessment of the training activities;
- the definition of guidelines on the international certification of inspectors for their participation in Joint Inspections regarding blood, cells and tissues, and ART.

In addition, the support to the implementation of the project activities will provide for:

- active involvement in the production and revision of the WP7 deliverables in order to guarantee their quality and consistency with the objectives of the Joint Action itself;
- guidelines regarding the international certification required for their participation in joint inspections, which is the core issue in WP8, covering the fields of blood, tissues and cells and ART.

The subcontractor undertakes to forward to ISS within the time allowed the documents and deliverables provided in the Specific CHAFEA-CONTRACT. The subcontractor undertakes to inform ISS of any modification regarding the organisation and performance of the task, such as a change in the structure or in the persons responsible for performing the latter.

## **Article 2**

The parties to this Sub Contract shall be bound *mutatis mutandis*, as far as relevant and applicable to a subcontract and not otherwise agreed in this Subcontract, by the term and conditions of the Specific CHAFEA-CONTRACT, which form part of this contract, but excluding provisions of the Specific CHAFEA-CONTRACT, that are particular to the Contractor alone.

Without prejudice to any other provision herein, the Sub Contractor shall provide the contractor with periodic and final reports in order to allow the Contractor to fulfil the obligations set in the article I.6 of the Specific CHAFEA CONTRACT .

The Subcontractor undertakes to accept the conditions under Articles 10.1, 10.2, 3, 17, 18, 20, 21, 22, and 30 of the General Conditions of the Specific CHAFEA-CONTRACT .

## **Article 3**

In return for the performance by subcontractor, ISS shall pay a price, in accordance to the details specified in the Financial Annex of the Specific CHAFEA-CONTRACT, equal of € 35.000,00.

Payments to the Sub Contractor will be made by ISS, after the receipt of the respective financial contribution from the CHAFEA, which will be paid as stated on article 4 and 5 of the Specific CHAFEA-CONTRACT: "Payment arrangements", as follows and after receiving of

regular invoice and the attestation, by the Scientific Supervisor dr. Giancarlo Maria Liembruno, of the regular execution of the activities:

⇒ € 3.500,00 as pre-financing after the signature of this subcontract;

⇒ € 21.000,00 within 90 days from the signing of the contract

⇒ € 10.500,00 to the delivery of the final results of the activities be made no later than May 31th, 2017.

For the above payments the Subcontractor will submit regular invoices making reference to the project and providing a detailed description of the tasks or supply concerned.

Invoices must be sent only via the Interchange System (SDI) managed by the Ministry of Economy and Finance , in accordance with Ministerial Decree 3 April 2013 n . 55. the data necessary for sending the electronic invoice are as follows :

**CODICE UNIVOCO UFFICIO (CUU): INBF9W**

Under penalty of nullity of the contract both parties assume the obligations of traceability of financial flows in accordance with art. 3, of the Italian Legislative Decree no. 136/2010.

Transactions relating to the performance of this contract will be performed by dedicated bank account in accordance with article 3, the Italian Law 13 August 2010 no. 136.

Notice is hereby given, in addition, within the terms of Italian Legislative Decree no. 136/2010, as amended by Italian Decree Law no 187/2010 in relation to the activities of this Act, the following:

"Smart CIG: Z131A4A12E":

"CODICE UNICO DI PROGETTO - CUP: I85I15001670005"

The dedicate current account for the Università Cattolica del Sacro Cuore: IBAN IT70A0200805314000102942763 UNICREDIT Agency Roma 60 , largo Agostino Gemelli 1, 00168 Rome

Any modification to the above bank account shall be made communicate at the Contractor address in writing.

This contract , drawn up in the form of the private , is subject to registration only in case of use , in accordance with art . 5 paragraph 2 of Presidential Decree n . 131/1986 , at the expense of the requesting party ;

The stamp duty, in according to Presidential Decree 26 october 1972 no 642, is paid by the Università Cattolica del Sacro Cuore

#### **Article 4**

This Sub Contract is not subject to VAT according to the article 72 co.3, n.3 of D.P.R.633/1972 of the Italian Law because in execution of the CE agreement n. 2008 1312.

#### **Article 5**

In respect of the Article 19, the Sub Contractor assigns to Contractor, exclusively, all the obtained in performance of this subcontract. Contractor shall only be granted ownership to the result of said industrial and/or intellectual property rights as well as the right of use after full payment of the agreed remuneration. Ownership and rights of use held by the Subcontractor may neither be mortgaged nor transferred as security.

The Subcontractor shall treat as confidential any information and data of a technical or commercial nature received by the contractor under this subcontract and declared to be confidential ("Confidential Information") and shall not proceed to publication or communication in connection with any such Confidential Information without the prior written consent of the Contractor for a period of five years after the termination of this Subcontract.

## **Article 6**

The Subcontractor is responsible for all damages deriving to Contractor from implementation of the Subcontractor's activities under this Subcontract in accordance with the following conditions.

The Subcontractor shall be responsible for applying scientific care and for complying with accepted scientific standards but not for actually achieving the research and development goal.

The liability of the Subcontractor, its legal representatives and agents in the case of violation of obligations and tort shall be limited to intent and gross negligence. Only in case of violation of essential contractual obligations (cardinal obligations) the Subcontractor, its legal representatives and agents shall also be liable in case of slight negligence. In any case, liability shall be limited to the foreseeable, contractually typical damages.

Should the Subcontractor neither fulfil the performance as agreed upon nor do so at the time due nor in the manner agreed upon, then the Contractor may only demand compensation in lieu of performance if the Contractor has unsuccessfully set an appropriate deadline for the performance by the Subcontractor including the statement that it would otherwise reject acceptance of the performance after the passing of that deadline.

In particular the Subcontractor will be responsible in accordance with the above if, because of his/her conduct, obligation of Contractor towards the CHAFEA will not be abided by totally or partially, as described by the contract. The Contractor shall notify the Subcontractor and set out the reasons of the suspension of the payment by registered letter with acknowledgment of receipt or equivalent.

## **Article 7**

The work to be performed under this Sub Contract shall be completed on the date of the approval by the Commission of the tasks to be performed by the Sub Contractor as defined in the Specific CHAFEA-CONTRACT.

## **Article 8**

The sub contract shall be governed by the law of the Republic of Italy.  
This agreement is drawn in English and all documents shall be in English.

## **Article 9**

This sub contract shall enter into force only after the last signature of the contracting parties.

**Article 10**

The Sub Contractor requests for modification of this Sub Contract and its Annex, will be present to the Commission only by written request of the Contractor.

**Annexes**

⇒ Specific CHAFEA Contract ; and its Annex;

Istituto Superiore di Sanità  
Financial Manager  
Dr. R.M. Martocchia

The SUBCONTRACTOR  
Università Cattolica del Sacro Cuore  
Managing Director  
Prof. M. Elefanti

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Date: .....

Date: .....